Duke | MARGOLIS CENTER for Health Policy

Understanding Priorities for the Use of Digital Health Technologies to Support Clinical Trials for Drug Development and Review

Virtual Public Meeting

March 28, 2023 | 1:00 pm – 4:15 pm ET

March 29, 2023 | 1:00 pm – 4:45 pm ET

Background and Meeting Objective:

The FDA defines digital health technologies (DHTs) as systems that use computing platforms, connectivity, software, and/or sensors, for healthcare and related uses. Many DHTs are small portable instruments that may be worn or used by trial participants and may allow remote data acquisition in clinical investigations evaluating medical products.

DHTs allow for measurement of a wide range of activities, behaviors, and functioning in real life settings that can be incorporated in trial endpoints during drug development. DHTs may also improve patient access to clinical trials over wide geographic areas, increase patient population diversity, and promote retention by reducing the burden involved in participating in trials by collecting data remotely. In addition, DHTs can facilitate direct collection of information from participants who are unable to report their experiences (e.g., infants, cognitively impaired individuals).

The US Food & Drug Administration, using a cooperative agreement with the Robert J. Margolis, MD, Center for Health Policy at Duke University, is hosting a public workshop to bring together key stakeholders, such as patients, biopharmaceutical companies, DHT companies, clinicians, and academics, to understand the priorities for the development of DHTs for use in clinical trials. This meeting will explore the challenges and opportunities related to the use of DHTs in clinical trials during the drug development process, focusing on actigraphy and other sensor-based measurements. Additionally, this public workshop meets a Prescription Drug User Fee Amendments (PDUFA VII) commitment to convene the first of a series of public workshops by the end of the second quarter (Q2), fiscal year (FY) 2023.

Workshop Agenda | Day One

1:00 pm **Welcome and Opening Remarks**

Mark McClellan, Duke-Margolis Center for Health Policy

Jacqueline Corrigan-Curay, US Food and Drug Administration

1:15 pm **Session 1: Perspectives on Use of DHTs in Clinical Trials**

Moderator: **Nancy Allen LaPointe**, Duke-Margolis Center for Health Policy

Objective: In this session, speakers from FDA Center for Drug Evaluation and Research (CDER) and the Digital Health Center of Excellence (DHCoE) will set the stage for the workshop by establishing the definition, scope, and context of DHT use, providing a high-level overview of DHTs used in drug trials, and identifying what information regulators are interested in learning during this workshop.

Presentations:

- **Leonard Sacks**, US Food and Drug Administration
- **Matthew Diamond**, US Food and Drug Administration
- **Lucy Cesnakova**, Digital Medicine Society

Moderated Panel Discussion and Q&A

Panelists:

- **Leonard Sacks,** US Food and Drug Administration
- **Matthew Diamond,** US Food and Drug Administration
- **Lucy Cesnakova,** Digital Medicine Society
- **Carrie Northcott,** Pfizer
- **Alicia Staley,** Medidata Solutions
- **Cindy Geoghegan,** Patient and Partners

2:50 pm **Break**

3:00 pm **Session 2: Impact of DHTs on Clinical Trial Accessibility and Diversity**

Moderator: '**Lola Fashoyin-Aje**, US Food and Drug Administration

Objective: In this session, panelists will discuss how the use of DHTs may improve clinical trial accessibility during drug development for different patient populations and what impact the use of DHTs might have on the diversity of trial populations in terms of age, gender, socioeconomic status, race, ethnicity, and other socio-demographic features.

Presentations:

- **Patrick Gee,** iAdvocate, Inc.
- **Klaus Gottlieb,** Eli Lilly and Company

Moderated Panel Discussion and Q&A

Panelists:

- **Patrick Gee,** iAdvocate, Inc.
- **Klaus Gottlieb,** Eli Lilly and Company
- **Wendy Camelo Castillo,** University of Maryland, Baltimore
- **Anne Peters,** University of Southern California
- **Reginald Swift,** Rubix LS

4:05 pm **Concluding Remarks**

Mark McClellan, Duke-Margolis Center for Health Policy

4:15 pm **Adjournment**

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Workshop Agenda | Day Two

1:00 pm **Welcome and Opening Remarks**

Mark McClellan, Duke-Margolis Center for Health Policy

1:10 pm **Session 3: Actigraphy in Clinical Trials to Support Drug Development**

Moderator: **Christina Silcox,** Duke-Margolis Center for Health Policy

Objective: The use of actigraphy is being explored in different medical conditions and patient populations. This session will feature presentations on actigraphy and its potential value as an outcome measure in clinical trials.

Presentations: Examples: Use of Actigraphy in Clinical Trials

- **Jeremy Wyatt,** ActiGraph
- **Steve Xu**, Northwestern University
- **Diane Stephenson**, Critical Path Institute
- **Abhinav Sharma**, McGill University
- **Jennifer Mammen**, University of Rhode Island

Moderated Panel Discussion and Q&A

Panelists:

- **Jeremy Wyatt,** ActiGraph
- **Steve Xu,** Northwestern University
- **Diane Stephenson,** Critical Path Institute
- **Abhinav Sharma,** McGill University
- **Jennifer Mammen,** University of Rhode Island

2:30 pm **Break**

2:40 pm **Session 4: Use of Other Sensor-Based DHTs in Clinical Trials for Drug Development**

Moderator: **Jennifer Goldsack**, Digital Medicine Society

Objective: This session will focus on the use of other sensor-based DHTs including mobile cardiac monitors, continuous glucose monitors, and environmental sensors. Speakers will discuss their potential use in different medical conditions and patient populations and will address suitable outcome measures.

Presentations:

- **Kuldeep Singh Rajput,** Biofourmis
- **Neeta Sharma,** Dexcom
- **Dina Katabi,** Emerald Innovations

Moderated Panel Discussion and Q&A

Panelists:

- **Kuldeep Singh Rajput,** Biofourmis
- **Neeta Sharma,** Dexcom
- **Dina Katabi,** Emerald Innovations

3:40 pm **Break**

3:50 pm **Session 5: Key Priorities for the Advancement and Integration of DHTs into Clinical Trials for Drug Development**

Moderator: **Christina Silcox,** Duke-Margolis Center for Health Policy

Objective: In this session, a multi-stakeholder panel will reflect on the themes in Sessions 1 through 4 and consider key elements to frame priorities for the development of DHTs in clinical trials.

Moderated Panel Discussion and Q&A

Panelists:

- **Danielle Friend,** Janssen Pharmaceuticals
- **Yuge Xiao,** Michael J. Fox Foundation
- **Leonard Sacks,** US Food and Drug Administration
- **Rebecca Nebel,** PhRMA

4:35 pm **Concluding Remarks**

Marianne Hamilton Lopez, Duke-Margolis Center for Health Policy

4:45 pm **Adjournment**

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